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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/724,631	10/01/96	MCCORMICK	M 700399.90053

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HM32/1118 □

EXAMINER

KUNZ, G

ART UNIT	PAPER NUMBER
	1623

DATE MAILED:

11/18/98

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	Examiner	Group Art Unit	

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

#### Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

#### Status

- Responsive to communication(s) filed on 10-27-97 & 6-11-98.
- This action is **FINAL**.
- Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

#### Disposition of Claims

- Claim(s) 1 - 24 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- Claim(s) \_\_\_\_\_ is/are allowed.
- Claim(s) 1-24 is/are rejected.
- Claim(s) \_\_\_\_\_ is/are objected to.
- Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - All  Some\*  None of the CERTIFIED copies of the priority documents have been received.
  - received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

#### Attachment(s)

- Information Disclosure Statement(s), PTO-1449, Paper No(s). 4  Interview Summary, PTO-413
- Notice of References Cited, PTO-892  Notice of Informal Patent Application, PTO-152
- Notice of Draftsperson's Patent Drawing Review, PTO-948  Other \_\_\_\_\_

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Prosecution was suspended in this case in the letter mailed December 4, 1997, due to a potential interference. Prosecution is now continued until allowable subject matter is identified.

Claims 1 - 24 are pending in the case.

The indicated allowability of claims 13-24 is withdrawn in view of the newly discovered references of Hengen, Arbige et al., Burrows et al., and Stephens et al. Rejections based upon the newly cited references follow.

### **35 USC 112, Second Paragraph Rejection**

Claims 8 and 13 - 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is rendered vague and indefinite because of the word "comprises". This term should be replaced with the more definite "is".

Similarly, claim 18 is rendered vague and indefinite by the term "comprises". The words "comprises" and "group" should be deleted and the word "is" inserted immediately after "molecule."

Claim 13 is rendered vague and indefinite because of the syntax. It is suggested that this claim be rewritten in the following manner:

"An aqueous composition for precipitating nucleic acids comprising an indicator molecule coupled to a carrier molecule, said carrier conjugate co-precipitates nucleic acid molecules from an aqueous solution along with sufficient salt and alcohol to effect said co-precipitation."

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Claims 14 - 24 are also rejected under 35 USC 112, second paragraph, because they depend from a rejected base claim (claim 13).

### **35 USC 102 Rejection**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 2, 3, 4, 5, 7, 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Hengen (TIBS 21, June 1996).

The claims are directed to a method for precipitating nucleic acids comprising the use of a coprecipitant having an indicator molecule covalently bound.

Hengen teaches that there already exists in the prior art a commercial product from Novagen called Pellet Paint<sup>TM</sup> which is a glycogen-based co-precipitant with a colored moiety bound to it. See page 225, center column, "Pretty in Pink". Thus, the person of skill in the art would immediately envision the instant method using this commercially available product.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 6 and 9-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hengen in view of Arbige et al. (4,927,644) or Burrows et al. (4,435,429) or Stephens et al. (4,769,327).

Claims 6 and 9 - 12 are directed to a method for precipitating nucleic acids using as the co-precipitant a polysaccharide covalently bound to an indicator molecule. Claim 6 requires the carrier molecule to be a Type III glycogen. Claims 9-10 lists specific indicator molecules. Claims 11-12 define the indicator molecule as a pH-responsive molecule. Claims 13-24 are directed to aqueous compositions of the polysaccharide-indicator conjugate along with sufficient salt and alcohol to promote precipitation.

The teachings of Hengen are set forth supra. While Hengen does not disclose the structure of the fluorescent dye used in Pellet Paint<sup>TM</sup>; Arbige et al. (column 7, Table 3) Stephens et al. (column 10, line 61), and Burrows et al. (column 6, lines 21) each disclose polysaccharide molecules with a dye molecule covalently attached. These blue polysaccharides are not used for precipitating DNA. However, it would have been obvious to the person of ordinary skill in the art at the time of the invention to have substituted the blue-polysaccharides disclosed by Arbige, Stephens, or Burrows for the pink dye taught by Hengen for the purpose of producing a structurally different conjugate of a glycogen which would also function to co-precipitate DNA. Thus both the method of using polysaccharide conjugates as well as aqueous stock solutions of said conjugate along with the requisite salt and alcohol to

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effect DNA precipitation would also have been obvious to the person wanting to make the precipitation as convenient as possible. Thus, the invention is prima facie obvious in the absence of clear and convincing evidence to the contrary.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kunz, whose telephone number is (703) 308-4623. The examiner can normally be reached on Tuesday through Friday from 6:30 AM to 4:00 PM. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marion Knodel, can be reached on (703) 308-4311. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

*Gary L. Kunz*  
GARY L. KUNZ  
PRIMARY EXAMINER  
GROUP 1200